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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
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Licensing Committee Report

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Report of December 14, 2005

ACTION

ACTION ITEM 1

That the Board of Pharmacy pursue a statutory change to update the definition of pharmacy to include prescription processing and review, patient consultation, drug utilization review, medication therapy management, and/or other cognitive pharmacy services for California patients. A pharmacy would not be required to store and dispense dangerous drugs and dangerous devices. Also, this proposed change would provide an option for California pharmacists practicing independently to be licensed as a "advice/clinical center pharmacy."

Discussion
Since December 2004, the Licensing Committee has been working to respond to inquiries and comments pertaining to the scope of practice of pharmacy, particularly to the practice of pharmacy outside of a traditional pharmacy setting, and to the provision of services to California patients by pharmacies, pharmacists, and ancillary staff outside state lines.

The Committee agreed to address these issues through its quarterly meetings. The board encouraged the Committee to develop a concrete proposal in anticipation of the implementation of provisions of the Medicare Modernization Act (MMA) addressing pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act.

Following an initial overview document prepared for the December 2004 meeting, a draft of proposed statutory changes was prepared for the March 2005 meeting. That draft was the basis for discussions and reactions at the March, June and September 2005 meetings.

As the Committee defined and discussed them, there were three primary areas in which further specification and possible statutory change was debated:

(1) Given what has been or may be an increase in the number of entities/premises, both within California and outside of California, that are mostly focusing on "prescription review" and/or "cognitive services" separate from and/or in the absence of traditional "pharmacy" tasks such as the actual filling of prescriptions and dispensing of drugs, what can or should the Board do to license those entities/premises, as "pharmacies" or otherwise;
(2) When those "review" or "cognitive" services are provided by out-of-state pharmacies or pharmacists to California patients, particularly when out-of-state pharmacists are not located in a licensed premises, should the Board require that: the out-of-state pharmacist have a California license, or an alternative California registration; that the pharmacist at least be affiliated with an entity, i.e., a "pharmacy," that is licensed in California; that out-of-state "pharmacies," however defined, have a pharmacist-in-charge (PIC) licensed in California; and/or should the Board depend on discipline by pharmacists' (and pharmacies') home states of licensure to ensure compliance;
(3) In order to conform California law to federal expectations, to permit California licensees to practice fully as professional pharmacists, and/or to maximize the opportunities available under Medicare Part D, should the definitions and scope of practice of pharmacy presently stated in Pharmacy Law be clarified by the Board.

One of the primary topics that the Committee discussed is the increase emphasis on provision of professional "cognitive services" (e.g., drug utilization review (DUR), medication therapy management (MTM) by pharmacists, which may or may not be provided out of a traditional "pharmacy" premises: (a) whether to license facilities, in California or outside of California, from which such services are provided (which do not otherwise fit the traditional definition of a "pharmacy") *at all*; and (b) if so, whether to license them as "pharmacies," some variant thereof, or as something else entirely.

The draft statutory proposal prepared for the March 2005 meeting assumed that facilities in which "pharmacy" was being practiced (whether "pharmacy" as in prescription-filling, or "pharmacy" as in consultation, MTMP, etc.) would need to be licensed as pharmacies. It identified three separate *types* of pharmacies for licensure: (i) "Intake/dispensing" pharmacies - traditional pharmacies; (ii) "Prescription processing" pharmacies - offering prescription review services for another pharmacy or other provider; and (iii) "Advice/clinical center" pharmacies – providing clinical/cognitive services directly to patients or providers. The draft assumed that the three types would not be mutually exclusive, i.e., a given facility could overlap.

There was considerable discussion and opposition to requiring California licensed pharmacists to be licensed as an "Advice/clinical center pharmacy." It was emphasized that the board needs to recognize the independent practice of pharmacists and the proposal did not. It was argued that the public is adequately protected by licensure of the pharmacist and additional licensure as a pharmacy was not necessary. The recommendation provides pharmacists with an option to be licensed as an "advice/clinical care pharmacy." **(Attachment A)**

It was also questioned why the board requires an entity that processes prescriptions to be licensed as a pharmacy. It was explained that the processing of prescriptions under current pharmacy law constitutes the practice of pharmacy and therefore, must be practiced in a licensed pharmacy. It is the location that would receive telephonic and electronic orders for prescriptions and maintain the prescription and patient information, directing the prescription to a particular pharmacy for filling and dispensing. While the pharmacy law authorizes a pharmacist to electronically enter a prescription or order into a pharmacy's or hospital's computer, the law does not allow other pharmacy personnel to process prescriptions under the supervision of a pharmacist. To allow such a practice outside a pharmacy would require explicit language. An option may be to allow the practice pursuant to a contract with a pharmacy as long as the original prescriptions records and record of the pharmacist's review be maintained by the filling pharmacy.

Another option discussed by the Committee was to license the facilities but not call them "pharmacies." Other options included (i) licensing such entities as "pharmacies" under the current definition(s), without revision, (ii) not licensing these entities at all, (iii) deferring the licensure of these entities to some other agency or (iv) awaiting some consensus at the national level about interstate cooperation thereon.

A summary of the amendments in Attachment A is as follows:

B&P § 4037 – Updates the definition of "pharmacy" to include a "dispensing pharmacy", a "prescription processing pharmacy" and an "advice/clinical center pharmacy." A pharmacy would not be required to store or dispense dangerous drugs and a California pharmacist practicing independently would not be required to be licensed as a "advice/clinical center pharmacy," however, the option would be available.

B&P § 4201 – Requires each application to conduct a pharmacy to specify the type or types of pharmacy and requires that the Board of Pharmacy be notified when there is a change to the pharmacy type either prior to or after licensure.

B&P § 4207 – Gives the Board the authority to investigate all matters related to the issuance of a pharmacy license including the furnishing of dangerous drugs or dangerous devices, or to the performance or provisions of prescription/drug order processing or review services and/or cognitive services.

ACTION ITEM 2

That the Board of Pharmacy update the definition of a nonresident pharmacy to include prescription review and processing, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for California patients. That the Board of Pharmacy amend B&P §4303 to strengthen the board's authority to discipline a nonresident pharmacy.

Discussion
The Committee also discussed whether and/or how to regulate those out-of-state pharmacists who provide cognitive services and/or prescription processing services to and/or for California patients and providers, particularly where those pharmacists are doing so not through affiliation with or employment by a licensed entity (e.g., nonresident pharmacy, advice center, or prescription processing center), but on a consulting or other non-site-specific basis. During all of the Committee's discussions of this issue, there has been acknowledgment of a need to balance the Board's primary duty to protect the public with its desire not to impede either patient access to services (particularly for California patients) or to create unnecessary barriers for pharmacists.

This issue has not arisen directly in the past, with regard to out-of-state pharmacists filling and/or dispensing prescription drugs, because until now those out-of-state pharmacists have worked in (or at least this has been the assumption) nonresident pharmacies that were themselves required to maintain licensure. So there has not previously been a perceived need to consider licensing out-of-state pharmacists separately (in California) from the entities in which they practice. However, the definition of a nonresident pharmacy needs to be updated to include all pharmacy services not just the distribution of prescription drugs. The definition would be updated consistent with the definition for California pharmacies. **(Attachment B)**

It appears that there may be an industry growth in the number of pharmacists in other states providing services to California patients or providers who are not permanently or indivisibly affiliated with any particular (licensed) premises. This seems particularly likely with regard to cognitive/prescription processing services, which due to imaging/file-sharing advances, are not nearly as tied to a particular "place" as are (or were) dispensing functions.

Other considerations arose from the Committee's discussion, including: whether to limit the requirement of California licensure to out-of-state pharmacists providing cognitive or prescription processing services, or to extend it to those dispensing medications as well; whether to require this licensure of all pharmacists providing such services to California patients and/or providers, or only those not affiliated with a licensed entity of some kind; whether to put primary responsibility for record-keeping pertaining to provision of services to California patients on the shoulders of a licensed entity, or on the shoulders of the pharmacist (whether or not licensed in California); and/or if out-of-state pharmacists are not required to be licensed in California, how best to enforce violations of (particularly, California) law committed by those pharmacists.

The wide-ranging discussion at the committee meetings seemed to acknowledge a possibility of choosing between (a) licensing all out-of-state pharmacists, (b) requiring out-of-state pharmacists to maintain some form of registration short of licensure, (c) licensing only entities under the auspices of which out-of-state pharmacists would (be required to) practice, and/or (d) requiring that the pharmacists-in-charge of these licensed entities also be licensed in California.

The draft statutory proposal provided to the Committee for consideration included a combination of (a), (c), and (d), requiring licensure for all out-of-state pharmacists providing cognitive

services or prescription processing services to California, and *also* requiring licensure of the pharmacist-in-charge of a nonresident pharmacy.

Concern was expressed that this requirement would be burdensome to nonresident pharmacies and out-of-state pharmacists. Various other options were discussed at the meetings such as a "registration program" for the nonresident pharmacist, some type of national license certification by the National Association of Boards of Pharmacy (NABP), reciprocity, and/or no additional licensure but a requirement that the out-of-state pharmacist meet California practice standards. Another possibility discussed was not require that the individual practitioner be licensed in California, instead require that the out-of-state pharmacist providing services (or drugs) to California patients practice under the auspices of an entity licensed as a nonresident pharmacy (or other form of site license), with a possible further requirement that the pharmacist-in-charge be a California licensee.

The NABP model rules require that a pharmacist providing telepharmacy services across state lines identify himself or herself to any patient as a "licensed pharmacist," notify patients of the jurisdiction in which he/she is currently licensed to practice pharmacy, and register (with relevant state boards) to practice telepharmacy across state lines and provide patients with the jurisdiction's Board address and phone number. Telepharmacy is defined as the provision of pharmaceutical care through the use of telecommunications and information technologies to patients at a distance.

Among the above-listed alternatives to requiring licensure of all out-of-state pharmacists (or at least the out-of-state pharmacist-in-charge (PICs) that have been discussed, two were presented to the Committee in a possible statutory form: (1) the possibility of a non-licensure "certification" of some sort (perhaps supported by NABP), which would require conformance to California standards; and (2) the possibility that licensure would not be required of out-of-state pharmacists so long as services delivered to any California patient were delivered under the auspices of a California-licensed pharmacy/entity.

The California Pharmacists Association (CPhA) provided a similar proposal that would require an out-of-state pharmacist providing cognitive pharmacy services to register as a nonresident provider of pharmacy services. **(Attachment C)**

The Licensing Committee took all the discussions into consideration and determined that the best approach now would be to update the definition of a nonresident pharmacy to include prescription review and processing, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state and amend B&P § 4303 to strengthen the Board's authority to discipline a nonresident pharmacy and not rely on the state where the pharmacy is located to take action first.

The Committee did not recommend that the pharmacist-in-charge of the nonresident pharmacy be licensed in California nor require a pharmacist whether practicing as an employee of a nonresident pharmacy or practicing independently and providing cognitive pharmacy services to California patients be licensed in California. The Committee stated that the current licensing

structure provided the necessary public protection if an out state pharmacist harms a California patient. If this should happen, the Board would rely on that state to take action. Currently California has such authority to take action against a California pharmacist should he or she harm a patient in another state. The committee did recommend that board amend B & P § 4301(j) and (o) to clarify the law to include violations of other state laws and regulations as unprofessional conduct.

A summary of the proposed amendments in Attachment B is as follows:

B&P § 4112 – Updates the definition of "nonresident" pharmacy to include prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in California.

B&P § 4120 – Requires each application for a nonresident pharmacy to specify the type or types of pharmacy for which the application is submitted and requires the Board to be notified when there is a change to pharmacy type either prior to or after licensure.

B&P § 4301 – Clarifies that a pharmacist would be subject to unprofessional conduct for violation of any statutes or regulations of this state, any other state or federal regulatory agency.

B&P § 4303 – Requires the Board to report any violation of laws or regulations by a nonresident pharmacy to the appropriate regulatory or licensing agency of the state in which a nonresident pharmacy is resident. Authorizes the Board to take appropriate action against a nonresident pharmacy on the same grounds that the Board may take action against a resident pharmacy license.

ACTION ITEM 3

That the Board of Pharmacy sponsor a statutory change to update the definition of pharmacy practice to reflect the existing practice and the professional development of pharmacists, amend the law to specify the recordkeeping requirements for pharmacists that practice outside a pharmacy and to pursue the suggested changes to B&P § 4052, which are technical in that subparts are being relocated to other sections of law, and amend B&P § 4306.5 regarding the unprofessional conduct of pharmacists.

Discussion
The Committee also considered proposed amendments to update the statutory definition(s) of practice as a pharmacist to (i) better conform to existing practice, (ii) emphasize the professional development of pharmacy, and/or (iii) maximize California pharmacist practice as recognized by Medicare Part D.

Many of the suggested amendments/revisions is to recognize in statute that the practice of pharmacy means far more than simply counting and dispensing medications, that it is a professional practice, and that licensed professional pharmacists can practice both within and

outside the four walls of a traditional pharmacy. The proposed changes also include the record keeping requirements that a pharmacist must maintain when practicing outside of a pharmacy, and includes additional acts or omissions that may be considered unprofessional conduct by a pharmacist. **(Attachment D)**

In addition, the committee discussed additional revisions to B&P § 4052, which essentially reduces the size of section 4052 and relocates subparts to sections 4052.1-4052.3.

A summary of the proposed amendments in Attachment D is a follows:

B&P § 4036 – Updates the definition of pharmacist and the authority for a pharmacist to practice pharmacy within or outside a licensed pharmacy.

B&P § 4050 – States that pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

B&P § 4051(a) – Provides the functions that are inherent to pharmacy practice such as interpreting, verifying, and implementing drug orders and prescriptions; dispensing pursuant to legitimate drug orders and prescriptions; ensuring proper drug storage, documentation, inventory, labeling and record-keeping; maintaining accurate, complete, and confidential patient profiles and records; supervising pharmacy technicians and other ancillary personnel in the pharmacy; designing and implementing quality assurance procedures and protocols; compounding drug products pursuant to prescription and for prescriber office use; maintaining safe, secure, and sanitary conditions in licensed premises; performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation; collaborating with prescribers and other care providers regarding patient care; implementing standardized procedures and protocols regarding patient care; administering or furnishing drugs or biologicals where permitted by law; initiating, adjusting, or implementing patient drug regimens where permitted by law; and such other pharmacy functions as are authorized by law.

B&P § 4051(c) – Specifies that it is unlawful for any person to perform prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for patients, prescribers, or other care providers in California unless it is a licensed California pharmacist.

B&P § 4051(d) – Includes "cognitive services" to the functions provided by licensed pharmacists and specifies the records that a pharmacist must maintain when providing cognitive services to patients. It requires the pharmacist to keep a complete log and description of all patient records and other patient-specific information, including any test results or other pertinent data, used, consulted or relied on by the pharmacist when performing cognitive services. The board also has the authority to define by regulation the required content of the log and description. The log and description must be maintained in a readily retrievable form, and provided to the board upon request. The records must be kept for a period of at least three years from the performance of such function. Where the pharmacist performs cognitive services in a licensed pharmacy, the

obligation to keep and maintain these records extends to the pharmacy, its pharmacist-in-charge, and to the pharmacist performing the function. Where the function to which the log and description is performed outside the premises of a licensed pharmacy, the obligation to keep and maintain the foregoing records extends only to the performing pharmacist.

B&P § 4052, 4052.1, 4052.2, 4052.3 – Makes technical amendments in that subparts of this section are being relocated to other sections of law. Clarifies in 4052 that the pharmacists may administer immunizations pursuant to a protocol with a prescriber. Current law states that a pharmacist may administer immunizations under the supervision of a prescriber outside a licensed health care facility.

B&P § 4306.5 – Adds to the unprofessional conduct provision for a pharmacist acts or omissions that involve the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regarding the dispensing of prescription drugs and/or the provision of cognitive services, acts or omissions that involve the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function and for pharmacists that practices outside of a pharmacy premise, unprofessional conduct may include acts or omissions that involve, the failure to maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

NO ACTION

Meeting Summary of December 14, 2005 (Attachment E)

Licensing Statistics (Attachment F)

Competency Committee Report (Attachment G)

Quarterly Status Report on Committee Goals for 2005/06 (Attachment H)

ATTACHMENT A

§ 4037.

(a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced ~~and where prescriptions are compounded~~. Only a "dispensing pharmacy," as defined in subdivision (b), may possess, prepare, manufacture, derive, compound, repackage, furnish, sell or dispense controlled substances, dangerous drugs, or dangerous devices. In all other respects, whenever the term "pharmacy" is used in this chapter, it shall be deemed to refer to every one of the types in subdivision (b).

(b) "Pharmacy" includes, but is not limited to:

(1) a "dispensing pharmacy," which is any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail;

(2) a "prescription processing pharmacy", which is any area, place, or premises described in a license issued by the board wherein personnel licensed by the board engage in and/or supervise drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, patient profile review, and allergy and drug-interaction review;

(3) an "advice/clinical center pharmacy," which is any area, place, or premises described in a license issued by the board wherein personnel licensed by the board provide cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management.

(~~b~~c) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

(d) "Pharmacy" shall not include a clinic licensed under Section 4180 or Section 4190.

§ 4201.

(a) Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) Each application to conduct a pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037. The applicant shall immediately notify the board of any requested addition, deletion, or other change in specified pharmacy type prior to licensure. After licensure, any change in specified pharmacy type shall be reported to the board, on a form to be furnished by the board, at least 30 calendar days prior to implementation or elimination of any activities permitted by the added, deleted, or changed type designation.

(~~b~~c) As used in this section, and subject to subdivision (~~e~~d), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(~~e~~d) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(~~d~~e) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(~~e~~f) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(~~f~~g) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(~~f~~gh) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(~~g~~hi) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(~~h~~ij) For licenses referred to in subdivisions (~~f~~g), (~~g~~h), and (~~h~~i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~(j) This section shall become operative on July 1, 2001.~~

§ 4207.

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices, or to the performance or provision of prescription/drug order processing or review services and/or cognitive services, that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedures Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

ATTACHMENT B

§ 4112. Nonresident pharmacies; registration; prerequisites and requirements; fee; application; contact lenses

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices directly to patients into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state, shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, and (3) all general partners, if any~~, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state~~. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or partner~~, or pharmacist~~.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

§ 4120.

~~(a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler pursuant to this chapter without registering as a nonresident pharmacy.~~

(~~b~~a) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.

(~~c~~b) Each application to conduct a nonresident pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037. The applicant shall immediately notify the board of any requested addition, deletion, or other change in specified pharmacy type prior to licensure. After licensure, any change in specified pharmacy type shall be reported to the board, on a form to be furnished by the board, at least 30 calendar days prior to implementation or elimination of any activities permitted by the added, deleted, or changed type designation.

(~~d~~d) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.

(~~e~~e) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state.

4301.

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.
Unprofessional conduct shall include, but is not limited to, any of the following:
(a) Gross immorality.
(b) Incompetence.
(c) Gross negligence.
(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.
(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.
(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.
(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or

administering or offering to sell, furnish, give away, or administer any controlled substance to an addict.
(j) The violation of any of the statutes of this state, any other state, or of the United States regulating controlled substances and dangerous drugs.
(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.
(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall
be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.
(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.
(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.
(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.
(p) Actions or conduct that would have warranted denial of a license.
(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.
(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.
(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy

that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code.
(t) This section shall become operative on January 1, 2006.

4303.

(a) ~~The board may deny, revoke, or suspend a nonresident pharmacy registration for failure to comply with any requirement of Section 4112, 4124, or 4340, for any significant or repeated failure to comply with Section 4074 or 4076, or for failure to comply with Section 11164 of the Health and Safety Code.~~ The board may report any violation of the laws and regulations of this state, any other state, or of the United States, including but not limited to any violation of this chapter or of the regulations established by the board, to the appropriate regulatory or licensing agency of the state in which a nonresident pharmacy is a resident.

(b) ~~The board may deny, revoke, or suspend a nonresident pharmacy registration for conduct that causes serious bodily or serious psychological injury to a resident of this state if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to initiate an investigation within 45 days of the referral~~. The board may deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, and/or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon such action might be taken against a resident pharmacy.

ATTACHMENT C

September 21, 2005

Licensing Committee
California State Board of Pharmacy
400 R Street, Ste 4070
Sacramento, CA 95814

Re: Development of Proposal for Pharmacy Performing Drug Utilization Review, Medication Therapy Management, Pharmacist Call Centers and Central Processing of Prescription Drugs for CA Patients

Dear Licensing Committee:

The California Pharmacists Association (CPhA) is providing comments regarding the above referenced subject which was set forth in a memorandum from the Licensing Committee dated June 3, 2005. While we understand that no formal action on this subject has been approved by the Board, we feel it is appropriate to submit comments to the memorandum so that the Licensing Committee and the Board as a whole can consider them in connection with further action on the subject.

From our review of the memorandum and its attachments, we understand that the Licensing Committee is attempting to develop a statutory scheme for regulating the practice of pharmacy beyond traditional dispensing activities. The proposed language appears to suggest that the avenue to achieve this is to expand the definition of a "pharmacy" to include any physical location at which a pharmacist conducts activities requiring licensure.

CPhA recognizes the Board's desire to address the appropriate regulation of the practice of pharmacy as it expands into areas distinct from handling and dispensing of drugs. However, CPhA does not believe that changing the definition of pharmacy is an appropriate and effective means of regulating those activities.

As the Board is aware, traditionally, pharmacies are facilities where dangerous drugs are stored, compounded and dispensed. Record keeping, supervision and other requirements related to the normal activities carried out at pharmacies are based on the storage and dispensing of drugs at that physical location. If the definition were expanded as set forth in the proposed language, then the regulatory scheme for a pharmacist would have to be applied to locations where a pharmacist would be acting within his/her scope of practice, unrelated to dispensing, storage, etc. However, the regulatory scheme for a pharmacy would make no sense when applied to locations where storage and dispensing does not occur. Indeed, this would cause substantial confusion for the profession, and might actually deter licensees from engaging in more comprehensive cognitive services because of the uncertainty of how they are

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regulated. Indeed, this could have the affect of deterring pharmacists from providing these services, leaving other health care professionals to fill the vacuum.

CPhA believes there is a more appropriate and effective approach to regulating non dispensing activities of pharmacists. Although we do not agree that the need for such language has been shown, we also believe there is a way to regulate non resident pharmacists providing services to California residents in a manner that is more effective and legally sustainable than the approach contained in the Board's proposal.

Based on the foregoing, CPhA recommends abandoning consideration of the statutory changes attached to the June 3rd memorandum. Instead, CPhA requests that the Board consider the alternative approach that is attached to this letter. We believe the attachment appropriately addresses the need to regulate non dispensing activities of pharmacists, including regulating the activities of pharmacists licensed outside California when those pharmacists are providing services to California residents.

Sincerely,

John A. Cronin, Pharm.D., J.D.
Senior Vice President and General Counsel

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Article 2.5 is added to the Business and Professions Code to read:

Article 2.5. Requirements for Pharmacists Providing Cognitive Pharmacy Services.

Section 4044. Except as otherwise provided in this chapter, it is unlawful for any person to perform any cognitive pharmacy services for, or pertaining to, or at the request of patients, prescribers, or other care providers in this state unless he or she is licensed or registered under this chapter. A pharmacist providing cognitive therapy services, as set forth in section 4045, shall comply with all of the requirements of this Article.

Section 4045. (a) The following definitions govern the provisions of this Article.

(1) "Pharmacist" means either a person issued a license by the board under section 4200, or a person registered under section 4047.

(2) "Cognitive pharmacy services" include clinical advice or information, telephonic or in-patient consultation, drug utilization review and medication therapy management, whether or not provided in a licensed pharmacy.

Section 4046. A pharmacist providing cognitive pharmacy services shall do all of the following:

(a) Comply with the provisions of section 4051.

(b) Document reports by patients and health care providers of adverse outcomes or consequences associated with the delivery of cognitive pharmacy services.

(C) Document medication errors occurring in connection with or discovered as a result of the delivery of cognitive pharmacy services.

(d) Maintain for a period of three years patient records related to the delivery of cognitive pharmacy services and other patient specific information in a readily retrievable form.

Section 4047. (a) It shall be unlawful for any individual residing outside the state to provide cognitive pharmacy service to an individual residing in the state unless the person registers as set forth in this section.

(b) Before an individual residing outside the state may provide cognitive pharmacy services to residents of the state the person shall register with the board as a non resident provider of cognitive pharmacy services. The board shall promulgate regulations governing the forms and procedures for registration.

(C) In order to qualify to register as a non resident provider of cognitive pharmacy services, a person must provide proof of licensure as a pharmacist in good standing in the state form which the services will be provided to California residents, and the entity on whose behalf the services will be provided. In addition, the person must execute a declaration provided by the board acknowledging that all services provided to California residents are subject to the provisions of this chapter and the regulations of the board, and that any material violation of the provisions of this chapter, the regulations of the board or conduct deemed by the board to be unprofessional is grounds for revocation of registration and the right to provide services to California residents.

ATTACHMENT D

§ 4036.

"Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of an unexpired and active pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy as authorized by this chapter.

§ 4050.

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

§ 4051.

(a) The holder of an unexpired and active pharmacist license issued by the board is vested with the authority and responsibility to perform the following functions inherent to pharmacy practice:

(1) Interpreting, verifying, and implementing drug orders and prescriptions;
(2) Dispensing pursuant to legitimate drug orders and prescriptions;
(3) Ensuring proper drug storage, documentation, inventory, labeling and record-keeping;
(4) Maintaining accurate, complete, and confidential patient profiles and records;
(5) Supervising pharmacy technicians and other ancillary personnel in the pharmacy;
(6) Designing and implementing quality assurance procedures and protocols;
(7) Compounding drug products pursuant to prescription and for prescriber office use;
(8) Maintaining safe, secure, and sanitary conditions in licensed premises;
(9) Performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation;
(10) Collaborating with prescribers and other care providers regarding patient care;
(11) Implementing standardized procedures and protocols regarding patient care;
(12) Administering or furnishing drugs or biologicals where permitted by law;
(13) Initiating, adjusting, or implementing patient drug regimens where permitted by law; and
(14) Such other pharmacy functions as are authorized by this chapter.

(ab) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist licensed under this chapter.

(c) Except as otherwise provided in this chapter, it is unlawful for any person to perform any prescription review, consultation, drug utilization review, medication therapy management, or

other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, unless he or she is a pharmacist licensed under this chapter.

(~~b~~d) Notwithstanding any other law, a pharmacist licensed under this chapter may authorize the initiation of a prescription or adjustment of a prescription, pursuant to Section 4052, and otherwise provide cognitive services, clinical advice or information, or patient consultation, if all of the following conditions are met:

(1) The cognitive service, clinical advice or information, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of cognitive services, patient and clinical consultation, and advice, and appropriately reviews that information before performing any of these functions.~~:~~

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) The pharmacist authorizing initiation or adjustment of a prescription, or cognitive services such as clinical advice, information, or patient consultation, sets forth a complete log and description of all patient records and other patient-specific information, including any test results or other pertinent data, used, consulted or relied on by the pharmacist during the performance of such function. The board may by regulation further define the required content of the log and description. This log and description shall be maintained in a readily retrievable form, and provided to the board upon request, for a period of at least three years from the date of performance of such function. The underlying patient records and other patient-specific information used, consulted or relied on by the pharmacist during the performance of such function may be maintained elsewhere and not kept with the log and description, so long as those records and that information are readily retrievable and provided to the board upon request for a period of at least three years from the date of performance of such function. Otherwise, a duplicate copy of the patient records and patient-specific information used, consulted or relied on shall become part of the records maintained. Where the function to which the log and description pertains is performed on the premises of a licensed pharmacy, the obligation to keep and maintain the foregoing records extends to the pharmacy and its pharmacist-in-charge, and to the pharmacist performing the function. Where the function to which the log and description pertains is performed outside the premises of a licensed pharmacy, the obligation to keep and maintain the foregoing records extends only to the performing pharmacist.

§ 4052.

(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded ~~medication~~ drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform ~~the following~~ procedures or functions in a licensed health care facility as authorized by Section 4052.1. ~~in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:~~

~~(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(B) Ordering drug therapy-related laboratory tests.~~

~~(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.~~

(5)~~(A)~~ Perform ~~the following~~ procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2. ~~in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):~~

~~(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(ii) Ordering drug therapy-related laboratory tests.~~

~~(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an~~

~~electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.~~

~~(B) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.~~

~~(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:~~

~~(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.~~

~~(ii) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.~~

~~(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.~~

~~(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.~~

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide cognitive services such as drug utilization review, medication therapy management, consultation to patients, and professional information, including clinical or pharmacological information, advice, or consultation, to other health care professionals.

(8)~~(A)~~ Furnish emergency contraception drug therapy ~~in accordance with either of the following~~as authorized by Section 4052.3.~~:~~

(9) Administer immunizations pursuant to a protocol with a prescriber.

~~(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.~~

~~(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the~~

~~board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.~~

~~(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.~~

~~(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.~~

~~(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.~~

~~(b)(1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.~~

~~(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.~~
~~(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized~~

~~medical organizations.~~

(be) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(cd) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(de) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

§ 4052.1.

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order ~~(the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility)~~.

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

§ 4052.2.

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with

policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order ~~(the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility)~~.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery.

§ 4052.3.

(a) Notwithstanding any other provision of law, a pharmacist furnish emergency contraception drug therapy in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(b) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(c) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(d) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this section.

(e) For each emergency contraception drug therapy initiated pursuant to this section, the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

§ 4052.41.

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

§ 4306.5.

(a) Unprofessional conduct for a pharmacist may include:

(1) aActs or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board;

(2) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices and/or with regard to the provision of cognitive services;

(3) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(b) For pharmacists who practice outside of a pharmacy premises, unprofessional conduct may include acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

ATTACHMENT E

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

LICENSING COMMITTEE
Meeting Summary

DATE: December 14, 2005

TIME: 9:30 a.m. – 12 noon

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505-1019

BOARD MEMBERS Ruth Conroy, Pharm.D., Chair
Clarence Hiura, Pharm.D.
John Jones, RPh, JD

STAFF PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Dennis Ming, Supervising Inspector

Jan Perez, Legislative Coordinator
Joshua Room, Deputy Attorney General

Call to Order

Committee Chair Ruth Conroy called the meeting to order at 9:30 a.m.

Competency Committee Report

Assistant Executive Officer Virginia Herold provided the statistics for the California Pharmacy Jurisprudence Examination (CPJE) from April 1, 2005 to September 30, 2005. The overall pass rate was 77.5%. She noted that the data from this time frame captures the recent 2005 graduates from the California schools of pharmacy. The NAPLEX scores associated with any candidate who took the CPJE during this six-month period as reported to the board are also displayed, regardless of when the NAPLEX may have been taken (it could have occurred outside the six-month reporting period as noted). The board reports the CPJE performance data at six-month intervals and the schools of pharmacy are provided copies of this report. The report is also posted on the board's web site.

Ms. Herold also reported that at the October meeting, the Board of Pharmacy approved the new content outline for the CPJE, which will be used beginning April 2006. All questions for the CPJE are developed according to this outline. The new content outline has been released publicly and is on the board's web site. It will also be published in the January 2006 board newsletter. The board's CPJE content outline does not include tasks tested by NAPLEX; these tasks were removed via analysis of the NAPLEX content outline.

Development of Proposal to Update the Definition and Requirements for Pharmacy, Nonresident Pharmacy, the Definition of Pharmacist Practice and Licensure of Out-of-State Pharmacists

Committee Chair Ruth Conroy reported that since December 2004, the Licensing Committee has been working to respond to inquiries and comments pertaining to the scope of practice of pharmacy, particularly to the practice of pharmacy outside of a traditional pharmacy setting, and to the provision of services to California patients by pharmacies, pharmacists, and ancillary staff outside state lines.

The Committee agreed to address these issues through its quarterly meetings. The board encouraged the Committee to develop a concrete proposal in anticipation of the implementation of provisions of the Medicare Modernization Act (MMA) addressing pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act.

Following an initial overview document prepared for the December 2004 meeting, a draft of proposed statutory changes was prepared for the March 2005 meeting. That draft was the basis for discussions and reactions at the March, June and September 2005 meetings.

The Committee defined and discussed three primary areas in which clarification and possible statutory change was substantially debated:

(1) Given what has been or may be an increase in the number of entities/premises, both within California and outside of California, that are mostly focusing on "prescription review" and/or "cognitive services" separate from and/or in the absence of traditional "pharmacy" tasks such as the actual filling of prescriptions and dispensing of drugs, what can or should the Board do to license those entities/premises, as "pharmacies" or otherwise;
(2) When those "review" or "cognitive" services are provided by out-of-state pharmacies or pharmacists to California patients, particularly when out-of-state pharmacists are not located in a licensed premises, should the Board require that: the out-of-state pharmacist have a California license, or an alternative California registration; that the pharmacist at least be affiliated with an entity, i.e., a "pharmacy," that is licensed in California; that out-of-state "pharmacies," however defined, have a pharmacist-in-charge (PIC) licensed in California; and/or should the Board depend on discipline by pharmacists' (and pharmacies') home states of licensure to ensure compliance;
(3) In order to conform California law to federal expectations, to permit California licensees to practice fully as professional pharmacists, and/or to maximize the

opportunities available under Medicare Part D, should the definitions and scope of practice of pharmacy presently stated in Pharmacy Law be expanded and/or further specified by the Board.

One of the primary topics of Committee discussion has been, in light of the apparently increased emphasis on provision of professional "cognitive services" (e.g., drug utilization review (DUR), medication therapy management (MTM) by pharmacists, which may or may not be provided out of a traditional "pharmacy" premises: (a) whether to license facilities, in California or outside of California, from which such services are provided (which do not otherwise fit the traditional definition of a "pharmacy") *at all*; and (b) if so, whether to license them as "pharmacies," some variant thereof, or as something else entirely.

The draft statutory proposal prepared for the March 2005 meeting assumed that facilities in which "pharmacy" was being practiced (whether "pharmacy" as in prescription-filling, or "pharmacy" as in consultation, MTMP, etc.) would need to be licensed as pharmacies. It identified three separate *types* of pharmacies for licensure: (i) "Intake/dispensing" pharmacies - traditional pharmacies; (ii) "Prescription processing" pharmacies - offering prescription review services for another pharmacy or other provider; and (iii) "Advice/clinical center" pharmacies – providing clinical/cognitive services directly to patients or providers. The draft assumed that the three types would not be mutually exclusive, i.e., a given facility could overlap.

There was considerable discussion and opposition to requiring California licensed pharmacists to be licensed as an "Advice/clinical center pharmacy." It was emphasized that the board needs to recognize the independent practice of pharmacists and the proposal did not. It was argued that the public is adequately protected by licensure of the pharmacist and additional licensure as a pharmacy was not necessary. The recommendation provides pharmacists with an option to be licensed as an "advice/clinical care pharmacy."

It was also questioned why the board requires an entity that processes prescriptions to be licensed as a pharmacy. It was explained that the processing of prescriptions under current pharmacy law constitutes the practice of pharmacy and therefore, must be practiced in a licensed pharmacy. It is the location that would receive telephonic and electronic orders for prescriptions and maintain the prescription and patient information, directing the prescription to a particular pharmacy for filling and dispensing. While the pharmacy law authorizes a pharmacist to electronically enter a prescription or order into a pharmacy's or hospital's computer, the law does not allow other pharmacy personnel to process prescriptions under the supervision of a pharmacist. To allow such a practice outside a pharmacy would require explicit language. An option may be to allow the practice pursuant to a contract with a pharmacy as long as the original prescriptions records and record of the pharmacist's review be maintained by the filling pharmacy.

Another option provided was to license the facilities but not call them "pharmacies." Other options included (i) licensing such entities as "pharmacies" under the current definition(s), without revision, (ii) not licensing these entities at all, (iii) deferring the licensure of these

entities to some other agency (e.g., Department of Health Services), or (iv) awaiting some consensus at the national level about interstate cooperation thereon.

The Licensing Committee recommended that the Board of Pharmacy update the definition of pharmacy to include prescription processing and review, patient consultation, drug utilization review, medication therapy management, and or other cognitive pharmacy services for patients in this state. Moreover, a pharmacy would not be required to store and dispense dangerous drugs. It would be an option for pharmacists practicing pharmacy independently to be licensed as a "pharmacy." The Committee determined that this was the best approach because it was consistent with other states and would not impede the independent practice of pharmacists in California.

The Committee then discussed whether and/or how to regulate those out-of-state pharmacists who provide cognitive services and/or prescription processing services to and/or for California patients and providers, particularly where those pharmacists are doing so not through affiliation with or employment by a licensed entity (e.g., nonresident pharmacy, advice center, or prescription processing center), but on a consulting or other non-site-specific basis. During all of the Committee's discussions of this issue, there was acknowledgment of a need to balance the Board's primary duty to protect the public with its desire not to impede either patient access to services (particularly for California patients) or to squeeze pharmacists out of the marketplace.

This issue has not arisen directly in the past, with regard to out-of-state pharmacists filling and/or dispensing prescription drugs, because until now those out-of-state pharmacists have worked in (or at least this has been the assumption) nonresident pharmacies that were themselves required to maintain licensure. So there has not previously been a perceived need to consider licensing out-of-state pharmacists separately (in California) from the entities in which they practice. However, the definition of a nonresident pharmacy needs to be updated to include all pharmacy services not just the distribution of prescription drugs. The definition would be updated consistent with the definition for California pharmacies.

While it appears that there may be an industry growth in the number of pharmacists in other states providing services to California patients or providers who are not permanently or indivisibly affiliated with any particular (licensed) premises, this seems particularly likely with regard to cognitive/prescription processing services, which due to imaging/file-sharing advances, are not nearly as tied to a particular "place" as are (or were) dispensing functions. Because of this, other considerations arose from the Committee's discussion, including: whether to limit the requirement of California licensure to out-of-state pharmacists providing cognitive or prescription processing services, or to extend it to those dispensing medications as well; whether to require this licensure of all pharmacists providing such services to California patients and/or providers, or only those not affiliated with a licensed entity of some kind; whether to put primary responsibility for record-keeping pertaining to provision of services to California patients on the shoulders of a licensed entity, or on the shoulders of the pharmacist (whether or not licensed in California); and/or if out-of-state pharmacists are not required to be licensed in California, how best to enforce violations of (particularly, California) law committed by those pharmacists.

The wide-ranging discussion at the committee meetings seemed to acknowledge a possibility of choosing between (a) licensing all out-of-state pharmacists, (b) requiring out-of-state pharmacists to maintain some form of registration short of licensure, (c) licensing only entities under the auspices of which out-of-state pharmacists would (be required to) practice, and/or (d) requiring that the pharmacists-in-charge of these licensed entities also be licensed in California.

The Committee considered a draft statutory proposal that provided a combination of (a), (c), and (d), requiring licensure for all out-of-state pharmacists providing cognitive services or prescription processing services to California, and *also* requiring licensure of the pharmacist-in-charge of a nonresident pharmacy.

Concern was expressed that the statutory proposal would be burdensome to nonresident pharmacies and out-of-state pharmacists. Various other options were discussed at the meetings such as a "registration program" for the nonresident pharmacist, some type of national license certification by the National Association of Boards of Pharmacy (NABP), reciprocity, and/or no additional licensure but a requirement that the out-of-state pharmacist meet California practice standards. Another possibility would be striking the requirement that the individual practitioner be licensed in California, instead requiring that the out-of-state pharmacist providing services (or drugs) to California patients practice under the auspices of an entity licensed as a nonresident pharmacy (or other form of site license), with a possible further requirement that the pharmacist-in-charge be a California licensee.

The NABP model rules require that a pharmacist providing telepharmacy services across state lines identify himself or herself to any patient as a "licensed pharmacist," notify patients of the jurisdiction in which he/she is currently licensed to practice pharmacy, and register (with relevant state boards) to practice telepharmacy across state lines and provide patients with the jurisdiction's Board address and phone number. Telepharmacy is defined as the provision of pharmaceutical care through the use of telecommunications and information technologies to patients at a distance.

Among the above-listed alternatives to requiring licensure of all out-of-state pharmacists (or at least out-of-state PICs) that have been discussed, two were presented as possible statutory form: (1) the possibility of a non-licensure "certification" of some sort (perhaps supported by NABP), which would require conformance to California standards; and (2) the possibility that licensure would not be required of out-of-state pharmacists so long as services delivered to any California patient were delivered under the auspices of a California-licensed pharmacy/entity.

The California Pharmacists Association (CPhA) provided a similar proposal that would require an out-of-state pharmacist providing cognitive pharmacy services to register as a nonresident provider of pharmacy services.

The Licensing Committee recommended that the Board of Pharmacy update the definition of a nonresident pharmacy to include prescription review and processing, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state. The committee also recommended that B&P § 4303 be amended to

strengthen the board's authority to discipline a nonresident pharmacy and not rely on the state where the pharmacy is located to take action first.

The Committee did not recommend that the pharmacist-in-charge of the nonresident pharmacy be licensed in California nor require a pharmacist whether practicing as an employee of a nonresident pharmacy or practicing independently and providing cognitive pharmacy services to California patients be licensed in California. The Committee concluded that there has not been a compelling argument or public need to change the current licensing structure. The Committee stated that if an out state pharmacist harms a California patient, then the board would rely on that state to take action. Currently the Board has such authority to take action against a California pharmacist should he or she harm a patient in another state. The committee did recommend that board amend B & P § 4301(j) and (o) to clarify the law to include violations of other state laws and regulations as unprofessional conduct.

The Licensing Committee discussed proposed amendments to update the statutory definition(s) of practice as a pharmacist to (i) better conform to existing practice, (ii) emphasize the professional development of pharmacy, and/or (iii) maximize the potential for California pharmacist practice reimbursement under Medicare Part D.

Many of the suggested amendments/revisions is to recognize in statute that the practice of pharmacy means far more than simply counting and dispensing medications, that it is a professional practice, and that licensed professional pharmacists can practice both within and outside the four walls of a traditional pharmacy.

In addition, the Committee discussed additional revisions to B&P 4052, which essentially reduces the size of section 4052 and relocates subparts to sections 4052.1-4052.3. These changes should be non-controversial.

The Committee recommended to the board that it amend the law to update the definition of pharmacist practice to reflect existing practice and the professional development of pharmacists, amend the law to reflect the recordkeeping requirements for pharmacists that practice outside a pharmacy and to pursue the suggested changes to section 4052,which are technical in that subparts are being relocated to other sections of law, and amend B & P 4306.5 regarding the unprofessional conduct of pharmacists.

2006 Meeting Dates

The Licensing Committee selected the following meeting dates for 2006: March 22 (Oakland), June 15 (Burbank), September 20 (Oakland), and December 6 (Burbank).

Adjournment

Licensing Committee Chair Ruth Conroy thanked everyone for participating and adjourned the meeting at 12 noon.

ATTACHMENT F

Board of Pharmacy Licensing Statistics - Fiscal Year 2005/06

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	79	153	117	75	168								592
Pharmacist (initial licensing applications)	32	439	149	13	215								848
Intern pharmacist	35	234	232	255	308								1064
Pharmacy technician	369	558	609	556	484								2576
Pharmacy	39	36	30	18	30	17							170
Sterile Compounding	14	10	1	1	3	0							29
Clinics	5	5	1	10	4	0							25
Hospitals	1	2	0	4	4	2							13
Non-Resident Pharmacy	2	7	5	3	5	4							26
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	0	1	0	2	0	0							3
Non-Resident Wholesalers	7	7	5	17	11	8							55
Wholesalers	2	19	2	9	5	1							38
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0							0
Designated Representatives	26	61	51	74	42	58							312
Issued													
Pharmacist	146	334	161	19	224								884
Intern pharmacist	42	140	272	219	260								933
Pharmacy technician	438	569	491	443	504								2445
Pharmacy	45	42	31	19	20	20							177
Sterile Compounding	5	5	12	5	4	4							35
Clinics	15	8	7	0	4	5							39
Hospitals	1	5	0	2	4	3							15
Non-Resident Pharmacy	9	3	7	2	3	4							28
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	0	3	0	0	1	2							6
Non-Resident Wholesalers	10	13	5	3	5	2							38
Wholesalers	5	5	5	4	6	0							25
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0							0
Designated Representatives	42	47	33	59	31	31							243

*Denotes updated to include pending files to process and processed pending files.

Board of Pharmacy Licensing Statistics - Fiscal Year 2005/06

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending*													
Pharmacist Examination	u/a	u/a	u/a	u/a	u/a	122							
Intern pharmacist	u/a	u/a	218	u/a	u/a	210							
Pharmacy technician	906	668	727	730	964	844							
Pharmacy	43	30	36	42	57	54							48
Sterile Compounding	38	40	33	32	29	32							54
Clinics	48	49	45	53	55	51							47
Hospitals	12	8	7	5	7	12							9
Non-Resident Pharmacy	19	20	14	15	12	11							34
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	1	1	1	4	2	2							5
Non-Resident Wholesalers	54	53	50	49	63	54							100
Wholesalers	24	22	24	24	32	27							67
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0							0
Designated Representatives	116	130	148	163	174	201							201
Change of Pharmacist-in-Charge													
Received	72	128	128	110	89	61							588
Processed	102	92	97	100	90	149							630
Pending	209	245	276	286	285	197							197
Change of Exemptee-in-Charge													
Received	2	2	0	9	5	12							30
Processed	2	2	0	6	4	11							25
Pending	8	8	8	11	12	13							13
Change of Permits													
Received	33	73	39	69	58	50							322
Processed	21	50	48	69	56	21							265
Pending	171	194	184	184	186	215							215
Discontinuance of Business													
Received	17	17	9	7	8	12							70
Processed	30	1	0	0	0	0							31
Pending	39	55	64	71	79	91							91

*Denotes updated to include pending files to process and processed pending files.

Board of Pharmacy Licensing Statistics - Fiscal Year 2005/06

Renewals Received	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pharmacist	1019	3078	1398	1362	1136								7993
Pharmacy technician	1279	3553	1500	1503	1348								9183
Pharmacy	591	592	903	493	242								2821
Sterile Compounding	11	44	21	22	7								105
Clinics	60	126	64	79	59								388
Non-Resident Pharmacy	21	26	15	17	9								88
Hypodermic Needle and Syringes	20	35	19	24	39								137
Non-Resident Wholesalers	26	52	23	30	23								154
Wholesalers	25	97	35	33	17								207
Veterinary Food-Animal Drug Retailer	1	3	2	0	1								7
Designated Representatives	111	320	151	132	68								782

The data for renewals received for December is not yet available.

*Denotes updated to include pending files to process and processed pending files.

ATTACHMENT G

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Board Members Date: January 23, 2006

From: Board of Pharmacy

Subject: Competency Committee Report

New Content Outline for CPJE

At the October 2005 board meeting, the board approved the use of the new content outline for the California Pharmacist Jurisprudence Examination (CPJE) given on or after April 1, 2006. The board posted the updated Content Outline on the Web site. The content outline that will be used until April 1, 2006, is posted on the Web site as well.

Candidates are being notified as of January 10, 2006, through the updated letter sent to candidates when they become eligible to take the CPJE, informing of them of the change in content outline and effective date of the change. The board has also notified by letter the candidates that were made eligible prior to January 10, 2006, but have not yet taken their CPJE examination.

Test Administration Contract

The Office of Examination Resources within the Department of Consumer Affairs is renewing its contract with a vendor to provide computer based testing. The board uses this contract to administer the CPJE. The current contract expires December 1, 2006. The request for proposal's advertisement publication date was December 2, 2005. The bid submittal deadline for the request for proposal is March 17, 2006. The anticipated contract award date is April 24, 2006. The duration of the contract is 3 years with 2 one-year optional extensions.

NAPLEX Passing Rates

The National Association of Boards of Pharmacy (NABP) recently reported the pass rates since implementing the North American Pharmacist Licensure Examination's (NAPLEX) new passing standard. This standard was developed by Thomson Prometric staff using an Angoff procedure with a panel of qualified

pharmacists representing a variety of backgrounds. A copy of the NABP letter is attached.

With the implementation of the new passing standard on May 1, 2005, the NAPLEX has had a slight decrease in passing scores as shown below:

	Second Trimester 2004	Second Trimester 2005	Change in Pass Rate
Passing rate of first-time candidates	97.38%	92.86%	4.52%
Passing rate for all candidates	95.11%	89.15%	5.96%

From the NAPLEX data, the impact on California schools' change in pass rates for first-time candidates is as follows:

First-Time Candidates	Second Trimester 2004 Candidates Pass / Fail		Second Trimester 2004 Pass Rate	Second Trimester 2005 Candidates Pass / Fail		Second Trimester 2005 Pass Rate	Change in Pass Rate
UCSF	118	0	100.00%	105	0	100.00%	No change
UOP	206	1	99.52%	155	3	98.10%	Decrease of 1.42%
USC	183	1	99.46%	155	1	99.36%	Decrease of 0.10%
Western	87	1	98.86%	75	0	100.00%	Increase of 1.14%

In comparison to the national data for schools, the California schools' change in pass rates for all candidates is as follows:

Total Candidates	Second Trimester 2004 Candidates Pass / Fail		Second Trimester 2004 Pass Rate	Second Trimester 2005 Candidates Pass / Fail		Second Trimester 2005 Pass Rate	Change in Pass Rate
UCSF	120	0	100.00%	104	1	99.05%	Decrease of 0.95%
UOP	216	1	99.54%	156	3	98.11%	Decrease of 1.43%
USC	189	1	99.47%	158	3	98.14%	Decrease of 1.33%
Western	92	1	98.92%	75	0	100.00%	Increase of 1.08%

CPJE Statistics

Attached is the CPJE statistical report for April 1, 2005 through September 30, 2005. The overall pass rate for the CPJE is 77.5%. The next report will cover performance data for 10/1/05-3/31/06. This report should be available at the April board meeting.

nabp

National Association of Boards of Pharmacy

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TO: EXECUTIVE OFFICERS - STATE BOARDS OF PHARMACY

FROM: Mary A. Dickson, Associate Executive Director

DATE: January 4, 2006

RE: NAPLEX Passing Rates

NAPLEX Passing Rates

As you are aware, the new NAPLEX passing standard was implemented with examinations administered beginning on May 1, 2005. The passing rate reported for the second trimester of 2005 reflects this new passing standard. A slight decrease in the NAPLEX passing rate of first-time candidates, a change from 97.38% in 2004 to 92.86% in 2005, has been observed and was expected. The decrease in overall and school NAPLEX passing rates has been attributed to the implementation of a new passing standard, which sets the lowest acceptable level of ability at a higher, validated level.

Although the passing rates have decreased from 2004 to 2005, the overall mean candidate ability estimate of first-time candidates who are graduates of accredited schools, on which NAPLEX scores are calculated, increased slightly. In both cases, the mean ability estimates were well above the minimally acceptable passing ability level.

The passing rate for all candidates testing in the second trimester of 2005 (89.15%) is slightly lower than that for the second trimester of 2004 (95.11%). For first-time test takers, the passing rate in the second trimester of 2005 (92.86%) was also lower than that for the second trimester of 2004 (97.38%).

When looking at the changes in school passing rates for first-time test takers:

- a total of nine schools (11%) had decreases greater than 10%;
- twenty-one schools (25%) had decreases between 5% and 10%, and 41 schools (49%), less than 5%;
- five schools (6%) experienced no decrease in passing rate, all with 100% passing rates for both time periods; and
- eight schools (10%) exhibited an increase in passing rate during the May 1 to August 31 trimesters 2004 to 2005.

NAPLEX Passing Rate Compared to Those of Other Health Care Professions

A comparison of the May 1, 2005 to August 31, 2005 passing rate of first-time NAPLEX candidates to those of other health care professions indicates that it is not out of line with others, and exceeds some. The passing rate of first-time candidates on the National Council of State Boards of Nursing Licensure Examination (NCLEX-RN) from April 2005 to June 2005 was 86% (www.ncsbn.org/pdfs/NCLEX_fact_sheet.pdf). The passing rates on the three parts of the United States Medical Licensing Examination in 2004 ranged from 89% to 94% (www.usmle.org/scores/2004perf.htm). First-time candidates from accredited programs taking the dental licensing examination achieved passing rates of 91.5% in July 2003 on part 1, and 94.9% in 2003 on the computer versions of part 2 (www.ada.org/prof/ed/testing/natboard/technical_nbde_04_report.pdf).

The New NAPLEX Passing Standard

The new NAPLEX passing standard was established through a standard-setting study. The study was conducted by Thomson Prometric staff using an Angoff procedure, one that is widely accepted by testing professionals and used by NABP. Qualified pharmacists sat on the panel, representing a variety of practice settings and including experienced and newly licensed pharmacists. NAPLEX Review Committee members and pharmacists recommended by state boards of pharmacy made up the panel.

If you have any questions, please contact me via phone at 847/391-4400 or 1-800/774-6227, or via e-mail at mdickson@nabp.net. Thank you.

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary

California State Board of Pharmacy
CPJE Statistics 4/1/05 – 9/30/05

The charts below display data for all candidates who took the CPJE examination between 4/1/05 through 9/30/05, inclusive.

The board also displays NAPLEX scores associated with any candidate who took the CPJE during this six-month period and was reported to the board, regardless of when the NAPLEX may have been taken (it could have occurred outside the six-month reporting period noted above).

The board reports CPJE performance data at six month intervals. The next report will cover performance data for 10/1/05-3/31/06.

Note: a candidate who took the CPJE twice during this period because he or she failed the examination would be counted twice. (California regulations and NABP requirements allow candidates who fail the examination to retake the failed examination after 90 days.)

Overall Pass Rates

CPJE

	Frequency	Percent
Fail	250	22.5
Pass	861	77.5
Total	1111	100.0

NAPLEX

	Frequency	Percent
Fail	43	4.1
Pass	1018	95.9
Total	1061	100.0

Data continues on next pages

Location of School

CPJE

			CPJE		CPJE Total	NAPLEX		NAPLEX Total
			Fail	Pass		Fail	Pass	
School	California 47.6%	Count	41	488	529	2	517	519
		Percent	7.8%	92.2		0.3%	99.6%	
	Other US 38.4%	Count	141	286	427	32	372	404
		Percent	33.0%	67.0%		7.9%	92.1%	
	Foreign 13.9%	Count	68	86	154	9	128	137
		Percent	44.2%	55.8%		6.6%	93.4%	
	Unclassified 0.1%	Count	0	1	1	0	1	1
		Percent		100.0%			100.0%	
Total		Count	250	861	1111	43	1018	1061
		Percent	22.5%	77.5%	100.0%	4.1%	95.9%	100.0%

Gender

			CPJE		CPJE Total	NAPLEX		NAPLEX Total
			Fail	Pass		Fail	Pass	
gender	F (68.9 %)	Count	181	584	765	29	702	731
		Percent	23.6%	76.3%		4.0%	96.0%	
	M (31.1 %)	Count	69	277	346	14	316	330
		Percent	19.9%	80.1		4.2%	95.8%	
Total		Count	250	861	1111	43	1018	1061
			22.5%	77.5%		4.1%	95.9%	

Degree

			CPJE		CPJE Total	NAPLEX		NAPLEX Total
			Fail	Pass		Fail	Pass	
degree awarded	BS Pharmacy (17.5%)	Count	90	104	194	13	158	171
		Percent	46.4%	53.6%		7.6%	92.4%	
	Pharm D. (82.5%)	Count	160	757	917	30	860	890
		Percent	17.4%	82.6%		3.4%	96.6%	
Total		Count	250	861	1111	43	1018	1061
			22.5%	77.5%		4.1%	95.9%	

California Schools

			CPJE		CPJE Total	NAPLEX		NAPLEX Total
			Fail	Pass		Fail	Pass	
school	UCSF (21.4%)	Count	14	99	113	1	107	108
		Percent	12.4%	87.6%		0.9%	99.1%	
	UOP (31.2%)	Count	9	156	165	0	165	165
		Percent	5.5%	94.5%			100.0%	
	USC (31.6%)	Count	11	156	167	0	164	164
		Percent	6.6%	93.4%			100.0%	
	Western U (15.9%)	Count	7	77	84	1	81	82
		Percent	8.3%	91.7%		1.2%	98.8%	
Total		Count	41	488	529	2	517	519
		Percent	7.8%	92.2%	100.0%	0.4%	99.6%	100.0%

US Schools of Pharmacy

		CPJE		Total
		Fail	Pass	
school graduated from	Auburn	0	1	1
	Samford	2	3	5
	U of AZ	1	8	9
	U of AR	0	2	2
	UCSF	14	99	113
	U of Pacific	9	156	165
	USC	11	156	167
	U of CO	0	8	8
	U of Conn	1	1	2
	Howard DC	2	0	2
	FL A&M	1	1	2
	U of FL	1	6	7
	Mercer	2	2	4
	U of GA	3	6	9
	Idaho SU	1	5	6
	U of IL Chi	4	3	7
	Butler U	0	2	2
	Purdue	1	1	2
	Drake	1	6	7
	U of IA	1	1	2
	U of KS	1	7	8
	U of KY	0	1	1
	NE LA U	0	1	1
	Xavier	1	3	4
	U of MD	2	7	9
	MA Col Pharm	22	48	70
	NE-MA	2	3	5
	Ferris	3	3	6
	U of MI	4	1	5

	Wayne SU	2	2	4
	U of MN	0	7	7
	U of MS	1	2	3
	St. Louis Col of PH	10	8	18
	UMKC	2	3	5
	Creighton	9	18	27
	U of NE	5	2	7
	U of NM	6	3	9
	Western	7	77	84
	A&M Schwartz	12	2	14
	St. Johns	5	1	6
	Union U	1	0	1
	UNC	2	1	3
	OH Nrthrn U	0	1	1
	OH State U	0	3	3
	U of Cinn	0	1	1
	U of Toledo	0	2	2
	SW OK State	1	0	1
	U of OK	0	1	1
	OR State U	0	7	7
	Duquesne	0	3	3
	Phl C of Pharm	3	3	6
	Temple	5	10	15
	U of Pitt	0	3	3
	U of PR	2	0	2
	U of RI	1	2	3
	Med U of SC	0	1	1
	U of TN	2	0	2
	TX SO U	0	1	1
	U of Hous	0	1	1
	U of TX	1	2	3
	U of UT	0	2	2
	Med C of VA	1	1	2
	U of WA	1	10	11
	WA State U	2	7	9
	U of WI-Mad	0	5	5
	U of WY	1	2	3
	Campbell U	0	2	2
	Nova Southeastern	1	2	3
	Wilkes University	0	1	1
	Bernard J Dunn	0	1	1
	Midwestern AZ	3	1	4
	Nevada College of Pharmacy	5	29	34
	MA School of Pharmacy - Worcester	1	3	4
	unclassified	0	1	1
	Other/FG	68	86	154
Total		250	861	1111

Graduating school location by country

		CPJE		Total
		Fail	Pass	
country	Armenia	0	1	1
	Bangledesh	1	0	1
	Brazil	1	0	1
	Canada	1	1	2
	Switzerland	0	1	1
	E&W Germany	0	1	1
	Egypt	2	9	11
	France	1	1	2
	United Kingdom	0	1	1
	Israel/West Bank/Gaza Strip	0	1	1
	India	27	18	45
	Iran	3	2	5
	Japan	1	0	1
	Jordan	0	2	2
	S. Korea	3	4	7
	Lebanon	1	2	3
	Malta	0	1	1
	Nigeria/New Guinea	0	2	2
	Peru	2	1	3
	Philippines	14	18	32
	Pakistan	1	0	1
	Puerto Rico	0	1	1
	Saudi Arabia	0	1	1
	Singapore	0	1	1
	USSR	1	0	1
	Syria	2	5	7
	Turkey	1	0	1
	USA	185	778	963
	Vietnam	0	1	1
	South Africa	3	8	11
Total		250	861	1111

ATTACHMENT H

Licensing Committee

2005-2006
Second Quarter Report
July 1, 2005 – December 31, 2005

Goal 2: **Ensure the professional qualifications of licensees.**

Outcome: **Qualified licensees.**

Objective 2.1: **Issue licenses within three working days of a completed application by June 30, 2006.**

Measures: **Percentage of licenses issued within 3 working days.**

A new tracking system has been implemented.

Tasks: **1. Review 100 percent of all applications within 7 working days of receipt.**

Note: Foreign graduate applications are not being processed (with a few exceptions) because of the changes outlined in SB 1913. Upon completion of the procedures and revision of the necessary forms, the board will resume this workload.

	Apps. Received:				**Average Days to Process:**			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	349	168*			12.5	5.9		
Pharmacist (initial licensing)	620	215*			4.1	3.4		
Pharmacy Intern	501	308*			8	10		
Pharmacy Technicians	1536	1040*			8	10		
Pharmacies	108	65			11	15		
Non-Resident Pharmacy	14	12			9	18		
Wholesaler	23	15			16	15		
Veterinary Drug Retailer	0	0			0	0		
Exemptee	138	174			6	5		
Out-of-State Distributor	19	36			19	15		
Clinics	11	14			13	14		
Hypo Needle & Syringe	1	2			1	5		
Sterile Compounding	25	4			2	5		

*Denotes October and November 2005 information available at time of report development.

2. **Process 100 percent of all deficiency documents within 3 working days of receipt.**

Average days to process deficiency:

	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	1-3	3		
Pharmacist (initial licensing)	1-3	1		
Pharmacy Intern	7	7		
Pharmacy Technicians	10	7		
Pharmacies	4	10		
Non-Resident Pharmacy	9	10		
Wholesaler	4	5		
Veterinary Drug Retailer	0	0		
Exemptee	1	1		
Out-of-State Distributor	4	5		
Clinics	2	12		
Hypo Needle & Syringe	1	1		

3. **Make a licensing decision within 3 working days after all deficiencies are corrected.**

Average days to issue license:

	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	3-5	1		
Pharmacist (initial licensing)	3-5	1		
Pharmacy Intern	5	5		
Pharmacy Technicians	5	5		
Pharmacies	3	2		
Non-Resident Pharmacy	5	5		
Wholesaler	5	5		
Veterinary Drug Retailer	0	0		
Exemptee	2	1		
Out-of-State Distributor	5	5		
Clinics	6	2		
Hypo Needle & Syringe	2	1		

4. **Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.**

	Q1	Q2	Q3	Q4
Pharmacist	641	243**		
Pharmacy Intern	454	479**		
Pharmacy Technician	1498	947**		
Pharmacies	124*	68		
Non-Resident Pharmacy	19*	9		
Wholesaler	15*	10		
Veterinary Drug Retailer	0	0		
Exemptee	122*	121		
Out-of-State Distributor	28*	10		
Clinics	30*	9		
Hypo Needle & Syringe	3*	3		
Sterile Compounding	22*	13		

*Denotes corrected since First Quarter Report.
** Denotes October and November 2005 information available at time of report development.

5. **Withdrawn licenses to applicants not meeting board requirements.**

	Q1	Q2	Q3	Q4
Pharmacy Technician	0	0		
Pharmacies	0	0		
Non-Resident Pharmacy	6	1		
Clinics	0	1		
Sterile Compounding	0	0		
Exemptees	23	17		
Hypo Needle & Syringe	1	0		
Out-of-State Distributor	6	5		
Wholesaler	5	2		

Objective 2.2: **Implement at least 50 changes to improve licensing decisions by June 30, 2006.**

Measure: **Number of implemented changes.**

Tasks:

1. **Review Pharmacist Intern Program.**

9/04 *Governor signed SB 1913 that contained new intern provisions to become effective 1/05.*

9/04 *Licensing Committee recommended changes to 1728 to implement SB 1913.*

9/04	*Licensing Committee recommended a change to 1719 to register interns who are enrolled in a school of pharmacy that has been granted "candidate status" by ACPE.*
9/04	*Licensing Committee recommended omnibus change to 1726 consistent with SB 1913.*
12/04	*Revised application and instructions to reflect changes from SB 1913 effective 1/1/05.*
10/05	*Revisions to 1719, 1720, 1726, 1727, and 1728 became effective. Regulation changes were necessary to implement SB 1915.*

2. Implement changes to the Pharmacy Technician Program.

1/04	*a. Use PTCB as a qualifying method for registration. – Completed.*
1/04	*b. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology. – Completed.*
9/04	*c. Eliminate clerk-typist from pharmacist supervisory ratio. Completed – regulation approved by OAL, change effective 10/3/04.*
9/04	*Enforcement Committee recommended technical changes to the regulatory requirements for pharmacy technicians.*
10/04	*Board approved the recommendation and will sponsor legislation in 2005.*
3/05	*SB 1111 (B&P Committee) was introduced.*
1/06	*Pharmacy technician provisions became effective.*

3. Administer a pharmacist licensure exam more than twice a year.

3/04	*Completed – CA applications began taking the NAPLEX and CPJE.*
9/05	*849 California applicants have taken the NAPLEX and 799 have taken the CPJE since July 1, 2005.*
10/05	*Released CPJE statistics for 4/1/05 – 9/30/05.*
1/06	*1,114 California applicants have taken the NAPLEX and 1,176 have taken the CPJE since July 1, 2005.*

4. **Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.**

10/05 *Contacted by instructors for potential new exam review course.*

5. **Develop statutory language to give the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.**

6. **Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.**

8/04 *Competency Committee met for two days and developed questions as well as the job analysis.*

9/04 *Competency Committee met for two days and developed questions.*

9/04 *Reported that board will recruit for new competency committee members in its next newsletter (scheduled for November).*

10/04 *Competency Committee met for two days and developed questions.*

11/04 *Job analysis will be released.*

12/04 *Job analysis released to 3,000 pharmacists.*

1/05 *Competency Committee met for two days and developed questions.*

2/05 *Competency Committee met for two days and developed questions.*

4/05 *Competency Committee met for two days and developed questions.*

8/05 *Competency Committee met for two days and developed questions as well as developed the updated Content Outline as a result of the job analysis.*

9/05 *Competency Committee met for two days and developed questions and reviewed the final draft of the Content Outline developed at the August Retreat. Committee forwarded Content Outline to the board for approval.*

10/05 *Competency Committee met for two days and developed questions.*

10/05 *Board approved new Content Outline for use beginning April 1, 2006.*

12/05 *New Content Outline placed on the Web site.*

7. Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.

6/04 *Completed*

9/04 *OAL approved the sterile compounding regulations and will become effective 10/29/04. The clean room requirements will take effect 7/1/05.*

9/04 *Reported that 13 sterile compounding licensed have been issued since July 1, 2004.*

1/05 *Reported that 29 sterile compounding licenses have been issued since July 1, 2004.*

6/05 *Reported that 56 sterile compounding licenses have been issued since July 1, 2004.*

9/05 *Reported that 24 sterile compounding licenses have been issued since July 1, 2005.*

1/06 *Reported that 35 sterile compounding licenses have been issued since July 1, 2005.*

8. Issue temporary permits whenever change of ownership occurs.

9/05 *1st Quarter – 28 temporary permits issued.*

1/06 *2nd Quarter – 13 temporary permits issued.*

9. Establish means for licensee to renew permits on line.

8/04 *Submitted Applicant Tracking System (ATS) report to the department.*

11/04 *Met with the department to discuss conversion to ATS and department prioritization.*

8/05 *Executive Officer participating as sponsor of iLicensing.*

8/05 *Staff begin working with programmers to define business processes for ATS system. Participate in bi-weekly meetings with programmer detailing business requirements.*

9/05 *Staff continue bi-weekly meetings with programmer detailing business requirements.*

9/05 *Staff attend demonstrations for iLicensing software and programs to allow for on-line renewal and applications.*

10/05	*Staff complete definition of business process and cashiering procedures with programmer for ATS*
10/05	*Staff attend demonstrations for iLicensing software and programs to allow for on-line renewal and applications.*
11/05	*iLicensing FSR submitted to Department of Finance.*
12/05	*iLicensing FSR approved.*

10. Implement Changes to Facilities Licensure Requirements

9/04	*Governor signed SB 1913 that included application requirements for all applicants.*
9/04	*Governor signed SB 1307 and AB 2682 to clarify the licensure of wholesale and non-resident wholesale facilities.*
9/04	*Staff with legal counsel reviewed application process for wholesalers and non-resident wholesalers.*
1/05	*New application forms are available for nonresident wholesalers.*
1/05	*New application forms are available for wholesalers.*
2/05	*Initiate review of clinic application requirements.*
3/05	*Initiate review of community pharmacy application requirements.*
3/05	*Initiate implementation of the surety bond requirement.*
6/05	*Submitted proposed change to clinic application requirement.*
8/05	*Staff complete draft forms to implement surety bond requirements for wholesalers and out of state distributors.*
9/05	*Staff begin working with consultant to modify existing system to accommodate changes in wholesaler and out of state distributor requirements.*
9/05	*Initiate review of pharmacy application requirements.*
9/05	*Initiate review of licensed sterile compounding application requirements.*
10/05	*Staff revise surety bond form. Form submitted to the Office of the Attorney General for approval*
10/05	*Article published in The Script detailing surety bond requirements.*
12/05	*Letters sent to wholesalers and out of state distributors notifying them bond requirements.*

12/05 *Testing begins on programming changes for the surety bond requirement.*

11. Review the Ownership of Pharmacies

7/04 *Counsel provided guidance on applicants who have prescriber spouses and/or a prescriber who shares a financial interest.*

12. Review the law regarding candidates who fail the pharmacist licensure exam 4 times or more who are required to take an additional 16 units of pharmacy education.

7/04 *Draft report provided to the board.*

9/04 *Governor signed SB 1913 to extend statutory provision to the board's next Sunset review date (2007).*

9/04 *Licensing Committee recommended omnibus regulation change to update section 1725 regarding acceptable pharmacy coursework for these candidates.*

12/04 *Report provided to the Legislature.*

13. Evaluate application requirements for all licenses.

9/04 *Governor signed SB 1913 that gives the board clear authority to request information needed to evaluate the qualifications of any applicant.*

9/04 *Licensing Committee recommended regulation changes to implement SB 1913 related to application process for the pharmacist licensure exam (1720).*

9/04 *Licensing Committee recommended a legislative change to eliminate the rules of professional conduct required with each application.*

9/04 *Licensing Committee recommended omnibus legislative changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.*

9/04 *Licensing Committee recommended changes to 1706.2 to require an eligible applicant to take the licensure exam within 1 year and obtain a license within 1 year of passing the exams.*

9/04 *Licensing Committee recommended a change to 1719 that authorizes an applicant to sit for the pharmacist licensure exam who has graduated from a pharmacy school granted "candidate" status by ACPE.*

10/04 *Board approved statutory proposal to eliminate the rules of professional conducted required for each application and omnibus changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.*

12/04	*Revised application and instructions to reflect changes from SB 1913 effective 1/1/05.*
3/05	*SB 1111 (B&P) introduced that contains statutory changes to eliminate "Rules of Professional Conduct."*
9/05	*SB 1111 passed.*
10/05	*Regulation changes to 1706.2 and 1719 became effective.*
1/06	*Eliminated Rules of Professional Conduct.*

14. Review the law regarding the educational requirements of graduates from foreign pharmacy schools.

9/04	*Governor signed SB 1913 that requires a foreign pharmacy school graduate to be certified by the Foreign Pharmacy Graduate Examination Committee.*
9/04	*Licensing Committee recommended that board amend its regulation to eliminate the foreign graduate evaluation application process and fee.*
9/04	*Sent a letter to all pending foreign graduates advising of law change and suspending application process.*
12/04	*Sent letter to all foreign graduate exam applicants not certified about revised exam eligibility status.*
10/05	*Regulation change to 1720.1 became effective. Regulation change necessary to implementation of SB 1913.*

15. Review the law regarding continuing education (CE) requirements for pharmacists.

7/04	*Board approved recommendations from the Pharmacy Foundation of California to update the CE statute and regulation.*
9/04	*Licensing Committee recommended changes to the CE statute to relocate from regulation the 30-hour requirement, to exempt all newly licensed pharmacist from CE requirements for two years and to renew the pharmacists license as "inactive" when a pharmacist fails to certify their CE credits.*
9/04	*Licensing Committee recommended revisions to the CE regulations.*
10/04	*Board approved recommended statutory and regulatory revisions to CE requirements.*
1/05	*SB 1111 (B&P) introduced that contains CE provision.*

6/05 *Reviewed the Pharmacist Self-Assessment Mechanism (PSAM) available from the National Association of Boards of Pharmacy (NABP) and determine options for pharmacists to obtain CE for completing the assessment. Determined what other competency assessments that available.*

9/05 *Licensing Committee recommended 6 hours of CE for completing PSAM.*

10/05 *Revised CE regulations became effective.*

10/05 *Board approved 6 hours of CE for the completion of PSAM.*

1/06 *Implementation of new CE provision regarding renewals of inactive pharmacists' license for failure to verify CE.*

16. Review the license of city and county jails and juvenile facilities.

8/04 *Staff met with Board of Corrections to discuss the dispensing process at these facilities and the regulatory structure, which have no effect of law.*

17. Review the certification process for foreign graduates that was implemented 1/05 and the Test of Spoken English (TSE requirement).

3/05 *Licensing Committee discussed the certification process and TSE requirement. Requested TSE presentation at future board meeting.*

18. Implement a temporary permit for a sterile compounding pharmacy.

9/05 *Submitted proposed statutory changes to Licensing Committee. Licensing Committee recommended board approval.*

10/05 *Board approved statutory proposal.*

19. Review the license of pharmacies in correctional facilities.

7/05 *Staff met with the Department of Corrections to discuss the distributions and dispensing process at these facilities and the regulatory structure of Pharmacy Law.*

11/05 *Received request from Department of Corrections.*

20. Review the licensure requirements for clinics.

3/05 *Proposal submitted to update the license requirements for clinics.*

6/05 *Licensing Committee recommended approval of statutory changes.*

7/05 *Board approved statutory changes to clinic requirements.*

12/05 *Met with representatives from the UC System regarding the license and distribution requirement.*

21. Review the request from University of Touro School of Pharmacy to be board recognized.

9/05 *Licensing Committee recommended approval to recognize University of Touro School of Pharmacy.*

10/05 *Board recognized the University of Touro School of Pharmacy.*

22. Participate in the Accreditation Council for Pharmacy Education (ACPE) evaluation of California schools of pharmacy.

1/05 *Board Member Ruth Conroy participated in the ACPE review of Loma Linda University School of Pharmacy.*

2/05 *Board Member Ken Schell participated in the ACPE review of UC San Diego School of Pharmacy.*

4/05 *Board Member Dave Fong participated in the ACPE pre-candidate review of University of Touro.*

23. Review the license requirements and drug distribution for clinics within the University of California.

12/05 *Met with representatives to discuss current requirements and the UC system drug distribution process.*

Objective 2.3:	**Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2006.**	
Measure:	**Number of public policy initiatives evaluated.**	
Tasks:	**1.**	**Explore the need to regulate pharmacy benefit managers.**
10/03		*Board concluded not to regulate PBMs.*
9/04		*Governor vetoed AB 1960 which would have required the regulation of PBMs by the Department of Managed Health Care.*
1/05		*AB 78 introduced to define PMBs and require specified disclosures to purchases.*
9/05		*Governor vetoed AB 78.*
	2.	**Explore the need to regulate drugs labeled for "veterinary use only."**
9/03		*SB 175 was introduced and signed (Chaptered 250, Statutes 2003).*
1/04		*Completed.*
	3.	**Explore the importation of drugs from foreign countries.**
7/04		*Discussed at July Board meeting.*
9/04		*Discussed at September Enforcement Committee meeting.*
9/04		*Governor vetoed SB 1449 which would have required the board to approve Web sites for Canadian pharmacies.*
10/04		*Discussed at October board meeting.*
12/04		*Discussed at December Enforcement Committee meeting.*
12/04		*HHS released its report of the Task Force on Drug Importation.*
1/05		*Discussed at January board meeting.*
3/05		*Discussed at March Enforcement Committee Meeting.*
4/05		*Discussed at April board meeting.*
6/05		*Discussed at June Enforcement Committee Meeting.*
7/05		*Discussed at July board meeting.*
9/05		*Discussed at September Enforcement Committee Meeting.*

10/05	*Discussed at October board meeting.*
12/05	*Discussed at December Enforcement Committee Meeting.*
	4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.
9/04	*OAL approved regulation change and will take effect 10/22.*
10/04	*Completed.*
	5. Establish a workgroup with DHS-State Food and Drug on pharmacy compounding
9/04	*Held third meeting of workgroup on compounding – proposed draft concept on general compounding.*
12/04	*Held fourth meeting of workgroup on compounding – recommending statutory proposal.*
12/04	*Licensing Committee recommended approval of statutory proposal to define general compounding and regulatory parameters.*
1/05	*Board approved general compounding proposal.*
2/05	*AB 595 was introduced and sponsored by the board.*
8/05	*AB 595 opposed by DHS – negotiating amendments.*
12/05	*AB 595 still pending.*
	6. Approve a statewide protocol for emergency contraception (ec) to permit pharmacists to furnish ec pursuant SB 490 (Chapter 651, Statutes of 2003.)
7/04	*Protocol on Web site.*
7/04	*Board approved regulation on protocol.*
9/04	*Regulation submitted to OAL for approval.*
11/04	*OAL approved regulation, which became effective 12/04.*
11/04	*Completed.*

7. Establish a regulatory structure to authorize the dispensing of drugs by veterinarian schools.

9/04 *Governor signed SB 1913 that provides authority.*

8. Consider a waiver pursuant to CCR, Title 16, Section 1706.5 from Cedars-Sinai Medical Center (CSMC) to conduct a study with UCSF, School of Pharmacy to determine the impact of using technician check technicians to fill unit dose cassettes on patient care.

4/04 *Board approved waiver for two years.*

7/05 *CSMC presented preliminary results of the study.*

9. Development of Proposal for Pharmacist Performing DUR, Medication Therapy Management, Pharmacist Call Centers and Central Processing of Prescriptions for CA patients.

12/04 *Licensing Committee discussed concepts related to proposal.*

3/05 *Licensing Committee discussed draft and proposal.*

6/05 *Licensing Committee discussed draft and proposal.*

9/05 *Licensing Committee discussed draft and proposal.*

12/05 *Licensing Committee recommended statutory amendments to update the definition of pharmacy practice by a pharmacist, a pharmacy and non-resident pharmacy.*

Objective 2.4:	**Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2006.**
Measure:	**Percentage of cashiered application and renewal fees within 2 working days.**
Tasks:	**1. Cashier application fees.**
9/05	*1st Quarter - The average processing time for processing new application fees is 2-3 working days.*
1/06	*2nd Quarter - The average processing time for processing new application fees is 2-3 working days.*
	2. Cashier renewal fees.
9/03	*The board lost its renewal cashier in October 2001 and has been unsuccessful in obtaining a freeze waiver to fill this position. The average processing time for processing renewal fees in house is 10 days.*
8/04	*Held interviews for renewal cashier because hiring freeze was lifted.*
10/04	*Filled vacancy for renewal cashier.*
9/05	*1st Quarter - Average processing time for central cashiering is 2-3 weeks.*
10/05	*Staff attend a user group meeting and discuss concern about processing time for central cashiering.*
1/06	*2nd Quarter - Average processing time for central cashiering is 2-3 week.*
Objective 2.5:	**Respond to 95 percent of all requests for - of licensing information within 5 working days by June 30, 2006.**
Measure:	**Percentage response for verifying licensing information within 5 working days.**
Tasks:	**1. Respond to requests for licensing verification.**
9/05	*1st Quarter – Processed 157 license verifications.* *(Updated to reflect statistics based on the fees collected)*
1/06	*2nd Quarter – Processed 169 license verification.* *(October and November 2005 information available at time of report.)*

Objective 2.6:	**Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.**
Measure:	**Percentage of licensing records changes within 5 working days**

Tasks:

1. **Make address and name changes.**

9/05 *1st Quarter – Processed 1,241 address changes.*

1/06 *2nd Quarter – Processed 1,525 address changes.*

2. **Process discontinuance of businesses forms and related components.**

9/05 *1st Quarter – Processed 31 discontinuance- of-business forms. Processing time is 30 days.*

1/06 *2nd Quarter – Processed 31 discontinuance- of-business forms. Processing time is 30 days.*

3. **Process changes in pharmacist-in-charge and exemptee-in-charge.**

9/05 *1st Quarter – Processed 291 pharmacist-in-charge changes. Average processing time is 14days. Processed 4 exemptee-in-charge changes. The average processing time is 5 days.*

1/06 *2nd Quarter – Processed 339 pharmacist-in-charge changes. Average processing time is 14 days. Processed 21 exemptee-in-charge changes. The average processing time is 5 days.*

4. **Process off-site storage applications**.

9/05 *Processed 14 off-site storage applications.*

1/06 *Processed 20 off-site storage initial applications and 5 reissued off-sites storage applications.*

5. **Process change-of-permit applications.**

9/05 *1st Quarter – Processed 119 applications. Average processing time is 30 days.*

1/06 *2nd Quarter – Processed 146 applications. Average processing time is 30 days.*